



## **21<sup>ST</sup> Century International Drug Terrorism**

### **Testimony by CMPI Director, Peter J. Pitts, to the Government Reform Committee Subcommittee on Criminal Justice, Drug Policy and Human Resources, November 1, 2005**

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The business of creating, distributing and selling counterfeit pharmaceutical products is an unregulated, criminal and growing part of the global economy.

When asked why he robbed banks, Willy Sutton, the depression-era desperado replied, “because that’s where the money is.” And if Sutton were alive today he’d be selling counterfeit prescription drugs. The bad news is that international prescription drug counterfeiting is on the rise. I estimate that globally, counterfeit pharmaceutical commerce will grow to become 16% of the aggregate size of the legitimate industry, a six percentage-point increase from 2004. This illegal business will generate \$75 billion in revenues for its owners in 2010, a 92% increase from 2005. Consider this – the growth in counterfeit drugs is outpacing the sale of legitimate pharmaceuticals and the Internet is becoming the 21<sup>st</sup> Century’s virtual drug cartel.

The World Health Organization (WHO) estimates that 8-10% of the global medicine supply chain is counterfeit – rising to 25% or higher in some countries. The largest counterfeit market with close proximity to the EU free trade zone is Russia, where the generally accepted estimate is that 12% of drugs are counterfeit. Now that the Baltic nations of Latvia, Lithuania, and Estonia have joined the European Union, WHO has warned that an increase in the risks of counterfeits entering the EU supply chain is “obvious.”

Two news items recently crossed the wires that illustrate this growing problem — and its truly global nature. The first story, from China, tells of eleven Chinese nationals and one American arrested in a counterfeit medicine scheme that spanned eleven countries, 440,000 bogus pills and \$4.3 million US dollars. The drugs being peddled were Lipitor, Viagra, Cialis and Levitra. The nations involved were the US, Great Britain, Switzerland and Israel. The second, more frightening news item comes from Hamilton, Ontario where a registered pharmacist, Abadir Nasr, was charged by Canadian federal authorities with selling counterfeit Norvasc heart medication after five customers who bought it died of heart attacks and strokes. Meanwhile, the Royal Canadian Mounted Police announced multiple investigations remain open in other parts of the country. Attention must be paid to this very serious global problem because it is nothing short of international health care terrorism.

I've just returned from Europe and they've got a lot of problems over there. One of them is that profiteers masquerading as pharmacists are selling unsafe, unregulated, mislabeled, repacked, and co-mingled drugs to unsuspecting consumers. In Europe the cause of this malaise is known as parallel trade -- and it's bad medicine.

According to the Treaty of Rome, parallel trade is completely legal and Articles 30 and 36 prohibit manufacturers from managing their European supply chains in their own or patients' interests. And counterfeiters are taking advantage of the opportunity.

For example, in 2002 a wholesaler in the Basel region was caught selling repackaged drugs to Germany worth SFr23 million (\$18 million). And two years later Swiss customs seized HIV medicines that had been stolen from a batch sent to Africa by the World Health Organization. Swissmedic, Switzerland's FDA, is also concerned about the quantity of fake drugs available on the Internet. According to the Swiss authorities there are 15 big cases in Europe right now, and "There is big money involved."

Last year 140 million individual drug packages were parallel imported throughout the European Union -- and a wholesaler repackaged each and every one. This means that, literally, parallel traders open 140 million packets of drugs, remove their contents and repackage them. But these parallel profiteers are in the moneymaking business, not the safety business. And mistakes happen. For example, new labels incorrectly state the dosage strength; the new label says the box contains tablets, but inside are capsules; the expiration date and batch numbers on the medicine boxes don't match the actual batch and dates of expiration of the medicines inside; and patient information materials are often in the wrong language or are out of date.

Drugs purchased from a British pharmacy and sent to an unknowing American consumer could come from European Union nations such as Greece, Latvia, Poland, Malta, Cyprus, or Estonia. In fact, parallel traded medicines account for about 20% (one in five) of all prescriptions filled by British pharmacies. In the EU there is no requirement to record the batch numbers of parallel imported medicines, so if a batch of medicines originally intended for sale in Greece is recalled, tracing where the entire batch has gone (for example, from Athens to London through Canada to Indianapolis) is impossible. Caveat Emptor is bad health care practice and even worse health care policy. Safety cannot be compromised, even if the truth is inconvenient. Facts are stubborn things and false profits result in deadly consequences.

Thank you